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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/971,099	10/03/2001	Cynthia C. Bamdad	M01015/70066 TJO	2127
23628	7590	10/06/2004	EXAMINER	
WOLF GREENFIELD & SACKS, PC			DO, PENSEE T	
FEDERAL RESERVE PLAZA			ART UNIT	
600 ATLANTIC AVENUE			PAPER NUMBER	
BOSTON, MA 02210-2211			1641	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/971,099

Applicant(s)

BAMDAD, CYNTHIA C.

Examiner

Pensee T. Do

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11 and 12 is/are rejected.
- 7) ☒ Claim(s) 9, 10 and 13-29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>July 23, 2003</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Amendment Entry & Claim Status***

The amendment filed on July 8, 2004 has been acknowledged and entered.

### ***Information Disclosure Statement***

The IDS filed on July 23, 2004 has been acknowledged and entered.

### ***Withdrawn Rejection(s)***

The rejection under 35 USC 112, 2<sup>nd</sup> paragraph is withdrawn herein.

The rejection under 35 USC 102(e) by Zhou is withdrawn herein.

### ***New Grounds of Rejection(s)***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 fails to further limit claim 13 since claim 19 depends on claim 16 and claim 16 depends on claim 15 which depends on claim 13. The limitation of claim 19 is exactly the same as that of claim 13.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 3-8, 11, 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Gombinsky et al. (US 6,409,925).

Gombinsky teaches a system and method for collecting and transferring magnetic particles from a plurality source vessel to a plurality of target vessels. The system comprises a plurality of collecting members each of which can be manipulated independently. Gombinsky further teaches a method for detecting biological entities being fluorescently labeled, wherein the entities are bound to magnetic particles. Each collecting member has a magnetic field providing member, which can be moved in two different positions. When the magnetic field providing member fits the tip of the collecting member, which is placed in a well or vessel that holds the magnetic particle, the magnetic field providing member collects the magnetic particle within said well. When the magnetic field providing member is raised or distanced from the tip, the particles are released into the well or a different well/vessel. In a system composed of a plurality of individual collecting members, one collecting member can be at the

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collecting position while the other collecting member can be at the releasing position. For example, in figure 2, the first collecting member is at a collecting position in which the magnetic particles are at the tip of the collecting member while the second collecting member is at a releasing position. Thus, in accordance with the present invention, the first collecting member in figure 2 magnetically draws/collects the magnetic particles/first article immobilized with a chemical or biological agent to a first position (the tip of the first collecting member) and the second collecting member draws/collects a second article/magnetic particles to a second location and releasing the second article/magnetic particles from the second location while holding the first article/magnetic particles on the first collecting member (see figures 1 and 2; col. 10, line 1-col. 12, line 18). The magnetic particles are capable of specifically binding to the biological entities. The specific binding, is typical carried out by attaching to the magnetic particle one member of a pair-forming group while the other is the biological entity to be detected. The biological entity is equivalent to the "first agent" of the present invention and is linked to a binding partner. The collecting member also comprises of an electromagnet so that when the electromagnet is turned off, the collecting member becomes deactivated and thus releasing the magnetic particles and vice versa. (see figure 3A and col. 7, line 66-col. 8, line 11; lines 61-70). The limitation of "The magnetic particle/first article immobilized to a signaling entity that is immobilized relative to the binding partner" is taught in Gombinsky at col. 8, lines 54-60. A label is reacted with an antibody carrying a label, such antibody is specific to the biological entity being detected. Regarding the first and second locations being predetermined areas of a surface, the tip of the collecting

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member satisfies this requirement because it is a predetermined area on the surface of said collecting member.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gombinsky et al. (US 6,409,925).

Gombinsky has been discussed above.

However, Gombinsky fails to teach the first chemical or biological agent is a drug candidate.

It would have been obvious to one of ordinary skills in the art to use the assay method of Gombinsky to detect or collect any target biological or chemical agent such as a drug candidate since Gombinsky teaches that the biological entities can be **any type of molecule**, complex of molecules or cells present in biological tissue. Those molecules include protein, peptides, amino acid, hormones, receptors, ligands, polysaccharides and **molecules that are laboratory produced** (see col. 8, lines 27-39). A drug candidate is a molecule that is laboratory produced.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection.

***Allowable Subject Matter***

Claims 9, 10 and 13-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior arts fail to teach that each of the first and second predetermined surface areas comprises an electrode; that the first article comprises of a magnetic bead and a colloid particle which is linked to the binding partner; said signaling entity is a the colloid particle which includes an auxiliary signaling entity immobilized thereto; and said signaling entity is a metallocene fastened to the colloid particle.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do  
Patent Examiner  
September 23, 2004



CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800/641

10/1/04